



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 24 1996

Mr. Bruce A. Schwemmer
President
Bruce EnviroExcel Group, Inc.
94 Buttermilk Bridge Road
Washington, New Jersey 07882

Dear Mr. Schwemmer:

This is in response to your letter of May 30, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements for your products:

"Bioseve 29/Infection"

Dietary supplement to nutritionally support a sense of well-being in people with head and chest infections.

"Bioseve 17/Articular Problems"

Dietary supplement to nutritionally support normal joint and muscle function.

We would point out that section 403(r)(6) of the act makes it clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for "Bioseve 29/Infection," however, suggests that this product is in fact intended for one of these purposes, in that it is intended to treat or mitigate a disease, namely, head and chest infections. Therefore, this claim does not qualify as a section 403(r)(6) claim. Use of this claim on the label or in the labeling of your product is likely to make it subject to regulation under the drug provisions of the act.

The brand name "Bioseve 17/Articular Problems" clearly implies that this product is intended for use by persons with diseases or other health conditions related to the joints of the body. Any representation that a product is intended for medical or therapeutic use may cause the product to be considered a drug. According to section 201(g) of the act, a drug is defined as articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals. The name "Bioseve 17/Articular Problems" suggests that this product is intended for other than food use within the meaning of section 201(g)(1)(B) of the act, in that it implies that the product is intended to treat persons with a disease, namely articular, or joint, disease. Therefore, the product name "Bioseve 17/Articular Problems" establishes that the product is intended for other than food use (i.e., it is intended to diagnose, cure, mitigate, treat, or prevent disease) and the

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product is a drug. A manufacturer who wishes to make claims under section 201(g)(1) of the act must contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, Division of Drug Labeling Compliance, Rm. 166 MPN, HFD-310, 7520 Standish Place, Rockville, Maryland 20855, and the product must be proven to be both safe and effective for its intended use.

We hope this information is helpful.

Sincerely yours,

James Tanner, Ph.D.
Acting Director
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Newark District Office, Office of Compliance, HFR-MA340

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200